UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PFIZER INC, ROBERT JARVIK, M.D., JARVIK HEART, INC., Plaintiffs, v. MATHEW I. GELFAND, M.D., Defendant.	x : : : : : : : : : x	Civil Action No. 08 Civ. 2018 (LAK) (JCF) ECF case

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS

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I. INTRODUCTION

It is indisputable that Gelfand's '688 patent claims only methods of administering a drug. Gelfand's Counterclaims do not allege that any of the Plaintiffs have performed any of the claimed methods. Instead, Gelfand's First Claim is based upon sale of a drug, not a method of administering it. Gelfand's Fourth Claim is based upon making a drug, not a method of administering it. Accordingly, there is no legally viable claim for direct infringement (35 U.S.C. § 271(a)) and claims One and Four should be dismissed.

It is clear that Gelfand has sued JHI without any substantive basis for asserting claims against it. Gelfand's belated assertion of an *alter ego* claim is not supported by the language of his Counterclaim and is legally insufficient to state such a cause of action. All claims against JHI should be dismissed.

It is also clear on the face of the pleadings and the relevant public record that Dr. Jarvik and JHI had no knowledge of the '688 patent during the alleged period of infringement such that they could be charged with infringement by knowingly inducing others to infringe. Gelfand's assertion that this constitutes a factual issue is belied by his own Counterclaim. Claim Two should be dismissed as to Dr. Jarvik and JHI.

Gelfand's claim of inducement of infringement by Dr. Jarvik and JHI on the basis of promotion of Caduet® is totally without factual foundation and is clearly rebutted by the contract between Pfizer and Dr. Jarvik. Gelfand makes no attempt to justify the filing of this claim.

Finally, Gelfand's alleged claim for infringement under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), is utterly without foundation in the statute as construed by the controlling precedent. Gelfand fails to even address the case law in his Memorandum. The necessary prerequisites for such a claim simply do not exist and Gelfand's contention to the contrary is frivolous. Gelfand's Third Claim should be dismissed.

Therefore, all claims against Dr. Jarvik and JHI and all claims of direct infringement against Pfizer should be dismissed on the face of the pleadings. In short, Gelfand has at best stated only one legally cognizable claim, albeit inaccurate and unsupportable, which is a claim against Pfizer for inducement of infringement.

II. ARGUMENT

A. The Standard on a Motion to Dismiss.

Under any standard, it is clear that Gelfand's Counterclaims (with the exception of the claim of induced infringement against Pfizer) fail to state a claim upon which relief can be granted. However, Gelfand's contention that the Supreme Court's decision in *Bell Atlantic Corp. v. Twombly*, ___ U.S. ____, ____, 127 S. Ct. 1955, 1965 (2007) has no effect on the standard applicable to this motion is incorrect.

Gelfand contends (at page 2-3 of Defendant's Memorandum of Law in Opposition to Plaintiff's Motion to Dismiss Defendant's Counterclaims,[1] hereinafter "Gelfand Mem. p __.") that the standard on a motion to dismiss for a claim of patent infringement has been unaltered by the decision in *Twombly*. For this proposition Gelfand cites two cases, *Erickson v. Pardus,* ___ U.S. ____, ____, 127 S. Ct. 2197, 2198 (2007) and *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354 (Fed. Cir. 2007).

Both cases are easily distinguished.

Erickson is not a patent case as Gelfand implies, but a prisoner's claim of a violation of the Eight Amendment protection against cruel and unusual punishment based upon his medical treatment in prison. Most importantly, the plaintiff-prisoner filed his complaint *pro se*. The Supreme Court recognized its long-standing rule that a "document filed *pro se* is to be liberally construed." *Erickson*, 127 S. Ct. at 2200, *citing Estelle v. Gamble*, 429 U.S. 97, 106, 97 S. Ct. 285, 292 (1976). Significantly, the Supreme Court found that the plaintiff had pled sufficient specific facts to support his claim. Both the District Court and the Court of Appeals had found

[1] Gelfand was granted two stipulated time extensions to file his Memorandum and then filed his Memorandum out of time, without a further request an extension of time.

that the prisoner had not sufficiently pled "cognizable independent harm." The Supreme Court reversed, finding petitioner's allegations of harm were sufficient. Significantly, the *Erickson* opinion makes only passing reference to *Twombly* and makes no attempt to curtail the higher standard of pleading recognized in *Twombly,* except arguably for *pro se* complaints.

Gelfand's reliance upon *McZeal* is equally misplaced. *McZeal* also concerned a *pro se* complaint which required application of considerable leeway on matters of pleading. 501 F.3d at 1356. Gelfand is not *pro se*, and no less stringent standard applies to his pleadings.

Further, *McZeal* recognized that a motion to dismiss for failure to state a claim is a purely procedural question not pertaining to patent law to which the Federal Circuit applies the law of the regional circuit. *Id.* at 1355-56; *C&F Packing Co., Inc. v. IBP, Inc.*, 224 F.3d 1296, 1306 (Fed. Cir. 2000). In the *McZeal* case, the Federal Circuit applied Fifth Circuit law to the issue. *McZeal*, 501 F.3d at 1356-58. This case is governed by Second Circuit law on the meaning and interpretation of *Twombly*.

The Second Circuit does not limit *Twombly* to its antitrust conspiracy context, but applies the higher pleading standard uniformly. Thus, in order for Gelfand to survive this motion to dismiss he "must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.' " *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (*quoting Bell Atl. Corp. v. Twombly*, *supra*); *see also Iqbal v. Hasty*, 490 F.3d 143, 158-59 (2d Cir. 2007) (declining to limit *Twombly* holding to the antitrust context).

Additionally, Gelfand agrees that the Court is entitled to take notice of the contract between Pfizer and Jarvik on this motion to dismiss. (Gelfand Mem. at 2.) However, Gelfand fails to respond to Plaintiffs' assertions that on review of a motion to dismiss it is appropriate for

the court to take judicial notice of public records and documents of which the non-moving party has notice,[2] such as documents referenced but not attached to a complaint or documents attached to a motion to dismiss. Taking notice of such documents does not convert Plaintiffs' motion to one for summary judgment. Gelfand has waived any argument to the contrary.

B. Gelfand's First Claim For Relief Fails To State A Claim For Direct Infringement.

Gelfand asserts that he "need only plead Defendant's sale of Gelfand's method to plead a claim of direct infringement under 35 U.S.C. § 271(a)." Gelfand then disingenuously asserts that "Gelfand has alleged that Defendants have sold and offered to sell his patented method invention, the '688 patent, in connection with their promotion and sale of Lipitor® and Caduet®." This is not what Gelfand's first claim for relief states:

> 47. In violation of 35 U.S.C. §271(a), Counter-Defendants, and each of them, have infringed and violated the '688 Patent by selling and offering to sell Lipitor® within the United States -- without authority of Dr. Gelfand -- for Lipitor®'s effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke.
>
> 48. In violation of 35 U.S.C. §271(a), Counter-Defendants, and each of them, have infringed and violated the '688 Patent by selling and offering to sell Caduet® within the United States -- without authority of Dr. Gelfand -- for Caduet®'s effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke.

These are not allegations that Plaintiffs have "sold" the method of the '688 patent. These are allegations that Plaintiffs have sold products -- Lipitor® and Caduet® -- for a subsequent allegedly infringed use. Gelfand's argument that he pled a sale of the method of the '688 patent is simply false.

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[2] In fact, Gelfand failed to provide any counter-statement of the facts and made no attempt in his brief to rebut any of Plaintiffs' factual contentions.

Gelfand's argument conflates the sale of Lipitor® and Caduet® for alleged use in the method of the '688 patent as the sale of the patented method itself. Even if Gelfand's allegations in his first claim for relief could be read to encompass sale of the method, the specific facts Gelfand has alleged belie the contention. Nowhere does Gelfand assert that Pfizer, Jarvik or JHI sold or offered to sell the method of the '688 patent. To the contrary, Gelfand repeatedly alleges that Plaintiffs have infringed the '688 patent by inducing patients to take Lipitor® and Caduet® in a manner that infringes the '688 patent.

These allegations, at best, allege direct infringement only by third parties (*i.e.*, patients), not by Pfizer, Dr. Jarvik or JHI. These allegations do not aver, and cannot aver, that the sale of Lipitor® or Caduet® directly infringes the '688 method claims. Direct infringement of the '688 patent requires that Pfizer, Jarvik or JHI themselves practice each step of the patented method and administer a drug to patients. Gelfand does not, and cannot, allege that they do. Sale of Lipitor® cannot constitute direct infringement of a method patent such as the '688 patent under 35 U.S. C. § 271(a). Accordingly, Gelfand's First Claim for Relief must be dismissed for failure to state a claim under Fed. R. Civ. P. 12(b)(6).

C. Gelfand's Fourth Claim For Relief Fails To State A Claim For Direct Infringement By Pfizer.

For the same reason, Gelfand's Fourth Claim for Relief must be dismissed. Gefland's Fourth Claim purports to allege that Pfizer directly infringes the '688 method of use claims under 35 U.S.C. § 271(a), "by making" Lipitor® and Caduet® "within the United States -- without authority of Dr. Gelfand . . . ." (Counterclaim ¶¶ 72, 73.) However, the Gelfand method of therapeutic use cannot be infringed simply by making Lipitor® or Caduet®. The '688 patent does not claim a method of making Lipitor® or Caduet®. "For process patent or method patent claims,

infringement occurs when a party performs all of the steps of the process." *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379 (Fed. Cir. 2007) (citations omitted).

Gelfand's assertion (Gelfand Mem. at 6) that *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336 (Fed. Cir. 2001) supports the proposition that "the manufacturer of a device may be liable for infringement even if his device is capable of non-infringing uses" is again wrong. The Federal Circuit's actual statement in *Hilgraeve* reads as follows:

> For example, in determining whether a **product claim** is infringed, we have held that an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of non-infringing modes of operation.

Id. at 1343 (emphasis added).

Nothing in *Hilgraeve* supports the proposition that a method claim can be directly infringed without the practice of the method. The '688 patent contains no claims to a drug *per se* or to a method of making a drug. Gelfand's patent can be directly infringed only when the claimed method is performed by the accused party. The making or selling of a product *per se* cannot constitute direct infringement even if, as Gelfand contends, the product may have an infringing use. Gelfand's Fourth Claim for Relief should be dismissed.

D. Gelfand Fails To State Any Claim Against JHI.

The sum total of the allegations against JHI in Gelfand's Counterclaims is that "[f]rom time to time since April 13, 2006, Jarvik, for his own benefit and for the benefit of JHI, has directly and indirectly infringed on the '688 patent . . . ." (Counterclaim ¶ 41.) This is insufficient to make JHI an infringer of the '688 patent. Gelfand pleads that only Dr. Jarvik entered into a personal services contract with Pfizer and only Dr. Jarvik received the proceeds due under that contract and only Dr. Jarvik promoted Lipitor® pursuant to that contract. (Counterclaim ¶¶ 32, 33.)

In his memorandum, Gelfand implicitly acknowledges the insufficiency of these allegations to set forth a claim of infringement by JHI, but asserts for the first time that JHI and Dr. Jarvik were *alter-egos*: "Gelfand has alleged facts that, if true, demonstrate that, for purposes of the sale and offering for sale of Lipitor®, JHI and Jarvik are to be treated as alter-egos and inextricable." (Gelfand's Mem. at 6.) However, there is no such allegation in the Counterclaims. Nor is there any factual basis for making such an allegation.

Moreover, even if Gelfand had pled that JHI and Jarvik "are to be treated as *alter-egos* and inextricable," this would not save the Counterclaims from dismissal. Pleading of the alter-ego relationship, such as is necessary to pierce the corporate veil demands significantly more.[3] There is a presumption of separateness between a corporation and its owners that must be overcome. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990) (the corporate entity should be recognized and upheld, unless specific, unusual circumstances call for an exception).

> Two elements must be pleaded to assert alter ego liability in New York: (1) the entity must exercise such dominion and control with respect to the transaction attacked that the subsidiary had no separate will of its own, and (2) the domination and control must be used to commit a fraud or wrong against the [Plaintiffs].

Levinson v. Primedia Inc., No. 02 Civ. 2222 (DAB), 2007 WL 2298406 (S.D.N.Y. Aug. 9, 2007), *citing American Protein Corp. v. AB Volvo*, 844 F.2d 56, 60 (2d Cir. 1988).

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[3] JHI is a New York corporation (Counterclaim ¶ 5), and as such New York law ordinarily applies to the alter-ego inquiry. *Kalb, Voorhis & Co. v. American Financial Corp.*, 8 F.3d 130, 132 (2d Cir. 1993), *citing* Restatement (Second) of Conflict of Laws § 307 (1971). Because the "alter ego issue is not unique to patent law," the Federal Circuit applies the law of the regional circuit. *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1380 (Fed. Cir. 2004). Although the alter-ego issue is a question of federal law, it usually "is determined by reference to state law. . . ." *U.S. v. Funds Held in Name or for Ben. of Wetterer,* 899 F.Supp. 1013, 1025 (E.D.N.Y. 1995). New York law and 2nd Circuit precedent appear to be largely indistinguishable on the *alter-ego* issue.

The Counterclaim nowhere avers that Dr. Jarvik exercised dominion and control over JHI. Nor does the Counterclaim assert that Dr. Jarvik used domination and control over JHI to commit a fraud or wrong against Gelfand. The Counterclaim avers that only Dr. Jarvik promoted Lipitor®, nowhere stating any action taken by JHI (Counterclaim ¶ 38). The sole allegation concerning JHI is that JHI benefited from the alleged infringement by Dr. Jarvik. (Counterclaim ¶¶ 38, 41.) This is insufficient as a matter of law to asset an *alter ego* claim.

All claims against JHI should be dismissed.

E. Gelfand Has Failed To Plead Notice Of The '688 Patent To Dr. Jarvik Or JHI Prior To The Termination Of Allegedly Inducing Activities And Therefore, Gelfand's Counterclaim Under 35 U.S.C. § 271(b) For Active Inducement Fail To State A Claim.

Gelfand does not contest that, as a matter of law, inducement of infringement requires specific intent to cause direct infringement and that knowledge of the existence of the patent in suit is essential to establish the specific intent to cause direct infringement. *DSU Med. Corp. v. JMS Co., Inc.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006); *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 161 F.3d 688, 695 (Fed. Cir. 1998) (plaintiff "cannot establish liability for inducing infringement of the '012 patent, because all accused acts by [defendant] occurred before [defendant] knew of the patent.").

Gelfand defends against dismissal of his Second Claim for Relief against Dr. Jarvik and JHI only by asserting, without a single supporting citation, that what Dr. Jarvik and JHI knew about the existence of the patent is an "issue of material fact." Gelfand's argument ignores the facts alleged in his Counterclaim.

Gelfand has alleged that Dr. Jarvik or JHI were placed on notice of the existence of the patent only by "sending a written request for a meeting with Jarvik" and Pfizer dated February 25, 2008. However, it is also incontestable that all activity by Dr. Jarvik in advertising and

promoting Lipitor® ceased on or before February 25, 2008, before Dr. Jarvik and JHI had received Gelfand's letter. (*See* Ebert Aff., Exhibit L.) Gelfand makes no attempt to deny this fact. Nor does he deny that the supporting documents are public records upon which this Court may rely on a motion to dismiss.

Hence, as a matter of law, Gelfand has failed to plead a legally cognizable claim for inducement under 35 U.S.C. § 271(b). Neither Dr. Jarvik nor JHI can have induced infringement of the '688 patent without knowledge of the patent. Accordingly, Dr. Jarvik and JHI should be dismissed from Gelfand's Second Claim for Relief.

F. Gelfand Has Stated No Claim With Respect To Active Inducement By Dr. Jarvik and JHI Relating to Caduet®.

Gelfand's Second Claim for Relief alleges that each of the Plaintiffs infringed the '688 patent by actively inducing doctors to prescribe Caduet® "within the United States -- without authority of Dr. Gelfand – to secure Caduet®'s effects beyond cholesterol-lowering, *i.e.*, as a chronically administered thrombolytic reagent in the treatment or prevention of cardiovascular disease, including heart attack and stroke." (Counterclaim ¶ 55.) However, the Counterclaims are specific that Dr. Jarvik endorsed only Lipitor® and engaged in no activity that could be construed as inducing infringement of the '688 patent by the use of Caduet®. This is confirmed by the contract between Pfizer and Dr. Jarvik, which related solely to Lipitor®. In fact, Dr. Jarvik never acted as a spokesperson for Pfizer on behalf of Caduet®. The facts alleged by Gelfand demonstrate conclusively that there was no active inducement by Dr. Jarvik or JHI by promotion of Caduet®.

Gelfand fails to respond to this argument in any manner. Gelfand's Second Claim for Relief should be dismissed as to Dr. Jarvik and JHI with respect to inducing infringement through the use of Caduet®.

G. Gelfand's Third Claim For Relief Fails to State a Claim Under 35 U.S.C. § 271(e)(2)(A)

Gelfand's Third Claim for Relief purports to state a cause of action for infringement of the '688 patent under the "Hatch-Waxman Act," 35 U.S.C. § 271(e)(2)(A). As detailed in Plaintiffs' opening Memorandum, Gelfand cannot state a claim for the technical infringement defined by this statute because: (i) Gelfand has no NDA to which Pfizer seeks to refer in a 505(j) or 505(b)(2) application, (ii) the '688 patent is not listed in the FDA Orange Book as covering Lipitor® or Caduet®[4], and (iii) no certification concerning the '688 patent has been made by Pfizer (or anyone else) to the FDA. The factual record is clear. None of these three requirements exists, and none is alleged to exist.

Gelfand responds by reasserting that the conclusory allegation of his Counterclaim asserting that Pfizer's applications for Lipitor® and Caduet® constituted 505(b)(2) applications are to be tested only after discovery. (Gelfand Mem. at 5.) Gelfand ignores the case law cited in Plaintiffs' opening Memorandum, most importantly the controlling Federal Circuit precedent and other persuasive authority which hold that a cause of action under 35 U.S.C. § 271(e)(2)(A) concerns an ANDA containing a Paragraph IV certification against a patent listed in the Orange Book for the drug in question. *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1326 (Fed. Cir. 2003); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 232 (4th Cir. 2002); *see also Eisai Co., Ltd. v. Mutual Pharmaceutical Co., Inc.*, No. Civ. A. 06-3613 (HAA), 2007 WL 4556958, at *11 (D.N.J. Dec. 20, 2007). Gelfand ignores the records of the FDA which establish conclusively that Pfizer's FDA applications for Lipitor® and Caduet® are not 505(b)(2) applications. Importantly, Gelfand ignores the fact that Gelfand's patent is not listed in the Orange Book for

[4] Orange Book Patent listings for any approved drug product are readily available on-line. http://www.fda.gov/cder/ob/default.htm.

Lipitor® or Caduet® and that no paragraph IV certification was ever filed to trigger the right to file suit under 35 U.S.C. § 271(e)(2)(A). Each of these is a requirement for assertion of a cause of action under 35 U.S.C. § 271(e)(2)(A) pursuant to the controlling precedents from the Federal Circuit. *Allergan, Inc. v. Alcon Labs., Inc., supra*; *aaiPharma Inc. v. Thompson*, *supra*. Even granting credence to Gelfand's unsupportable allegation that Lipitor® and Caduet® were somehow described or approved under section 505(b)(2) (and they were not), it is not disputed that no Orange Book listing exists and that no paragraph IV certification was made. This is fatal to Gelfand's claim.

Gelfand has not stated a claim for relief under 35 U.S.C. § 271(e)(2) and his Third Claim for Relief must be dismissed.

III. CONCLUSION

Once again, Gelfand has needlessly multiplied these proceedings by the assertion of frivolous claims. For the reasons set forth above, Plaintiffs' Motion to Dismiss Defendant's Counterclaims should be granted.

Respectfully Submitted,

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